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FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT

Risk Assessment Forum
U.S. Environmental Protection Agency
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ACKNOWLEGEMENTS

This U.S. Environmental Protection Agency (EPA) report has been developed under the auspices of EPA's Risk Assessment Forum, a standing committee of EPA scientists charged with developing risk assessment guidance for Agency-wide use. An interoffice work group chaired by Susan Norton (Office of Health and Environmental Assessment), Donald Rodier (Office of Toxic Substances), and Suzanne Marcy (Office of Water) led this effort. Other members of the work group are Michael Brody, David Mauriello, Anne Sergeant, and Molly Whitworth. William van der Schalie and William Wood of the Risk Assessment Forum staff coordinated the project, which included peer review by scientists from EPA, other Federal agencies, and the private sector.

FOREWARD

Publication of this report, "Framework for Ecological Risk Assessment" (Framework Report), is a first step in a long-term program to develop risk assessment guidelines for ecological effects. EPA has been developing risk assessment guidelines primarily for human health effects for several years. In 1986, EPA issued five such guidelines, including cancer, developmental toxicity, and exposure assessment (51 Federal Register 33992-34054, 24 September 1986). Although EPA had issued guidance for cancer risk assessment 10 years earlier (41 Federal Register 21402, 1976), the 1986 guidelines substantially enlarged the scope of EPA's formal guidance by covering additional health topics and by covering all areas in much greater depth. Each of the guidelines was a product of several years of discussion and review involving scientists and policymakers from EPA, other Federal agencies, universities, industry, public interest groups, and the general public.

Preliminary work on comparable guidelines for ecological effects began in 1988. As part of this work, EPA studied existing assessments and identified issues to help develop a basis for articulating guiding principles for the assessment of ecological risks (U.S. EPA, 1991). At the same time, EPA's Science Advisory Board urged EPA to expand its consideration of ecological risk issues to include the broad array of chemical and nonchemical stressors for which research and regulation are authorized in the environmental laws administered by EPA (U.S. EPA, 1990b). As a result, EPA has embarked on a new program to develop guidelines for ecological risk assessment. Like the program for health effects guidance, this activity depends on the expertise of scientists and policymakers from a broad spectrum and draws principles, information, and methods from many sources.

In May 1991, EPA invited experts in ecotoxicology and ecological effects to Rockville, Maryland, to attend a peer review workshop on the draft Framework Report (56 Federal Register 20223, 2 May 1991). The workshop draft proposed a framework for ecological risk assessment complemented by preliminary guidance on some of the ecological issues identified in the draft. On the basis of the Rockville workshop recommendations (U.S. EPA, 1991), the revised Framework Report is now limited to discussion of the basic framework (see figure 1), complemented by second-order diagrams that give structure and content to each of the major elements in the Framework Report (see figures 2 through 4). Consistent with peer review recommendations, substantive risk assessment guidance is being reserved for study and development in future guidelines.

The Framework Report is the product of a variety of activities that culminated in the Rockville workshop. Beginning early in 1990, EPA work groups and the National Academy of Sciences' (NAS) Committee on Risk Assessment Methodology began to study the 1983 NAS risk assessment paradigm (NRC, 1983), which provides the organizing principles for EPA's health risk guidelines, as a possible foundation for ecological risk assessment. Early drafts of EPA's Framework Report received preliminary peer comment late in 1990.

In February 1991, NAS sponsored a workshop in Warrenton, Virginia, to discuss whether any single paradigm could accommodate all the diverse kinds of ecological risk assessments. There was a consensus that a single paradigm is feasible but that the 1983 paradigm would require modification to fulfill this role. In April 1991, EPA sponsored a strategic planning workshop in Miami, Florida. The structure and elements of ecological risk assessment were further discussed. Some participants in both of these earlier meetings also attended the Rockville workshop. EPA then integrated information, concepts, and diagrams from these workshop reviews with EPA practices and needs to propose a working framework for interim use in EPA programs and for continued discussion as a basis for future risk assessment guidelines.

Use of the framework described in this report is not a requirement within EPA, nor is it a regulation of any kind. Rather, it is an interim product that is expected to evolve with use and discussion. EPA is publishing the Framework Report before proposing risk assessment guidelines for public comment to generate discussion within EPA, among Government agencies, and with the public to develop concepts, principles, and methods for use in future guidelines. To facilitate such discussion, EPA is presenting the framework at scientific meetings and inviting the public to submit information relevant to use and development of the approaches outlined for ecological risk assessment in the report.

Dorothy E. Patton, Ph.D.
Chair
Risk Assessment Forum

PREFACE

Increased interest in ecological issues such as global climate change, habitat loss, acid deposition, reduced biological diversity, and the ecological impacts of pesticides and toxic chemicals prompts this Framework Report. This report describes basic elements, or a framework, for evaluating scientific information on the adverse effects of physical and chemical stressors on the environment. The framework offers starting principles and a simple structure as guidance for current ecological risk assessments and as a foundation for future EPA proposals for risk assessment guidelines.

The Framework Report is intended primarily for EPA risk assessors, EPA risk managers, and persons who perform work under EPA contract or sponsorship. The terminology and concepts described in the report may also assist other regulatory agencies, as well as members of the public who are interested in ecological issues.

CONTRIBUTORS AND REVIEWERS

This report was prepared by members of the EPA technical panel listed below, with assistance from the staff of EPA's Risk Assessment Forum. Technical review was provided by numerous individuals, including EPA scientists and participants in the May 1991 peer review workshop. Editorial assistance was provided by R.O.W. Sciences, Inc.

Technical Panel

Co-Chairs

Suzanne Macy Marcy (through December 1990)
Office of Water

Susan Braen Norton
Office of Research and Development

Donald J. Rodier
Office of Toxic Substances

Members

Michael S. Brody
Office of Policy, Planning and Evaluation

David A. Mauriello
Office of Toxic Substances

Anne Sergeant
Office of Research and Development

Molly R. Whitworth
Office of Policy, Planning and Evaluation

Risk Assessment Forum Staff

William H. van der Schalie
Office of Research and Development

William P. Wood
Office of Research and Development

Reviewers

M. Craig Barber
U.S. Environmental Protection Agency
Environmental Research Laboratory
Athens, GA

Richard S. Bennett, Jr.
U.S. Environmental Protection Agency
Environmental Research Laboratory
Corvallis, OR

Steven Bradbury
U.S. Environmental Protection Agency
Environmental Research Laboratory
Duluth, MN

Janet Burris
U.S. Environmental Protection Agency
Office of Emergency and Remedial Response
Washington, DC

David W. Charters
U.S. Environmental Protection Agency
Office of Solid Waste and Emergency Response
Edison, NJ

Patricia A. Cirone
U.S. Environmental Protection Agency
Region 10
Seattle, WA

James R. Clark
U.S. Environmental Protection Agency
Environmental Research Laboratory
Gulf Breeze, FL

Robert Davis
U.S. Environmental Protection Agency
Region 3
Philadelphia, PA

Anne Fairbrother
U.S. Environmental Protection Agency
Environmental Research Laboratory
Corvallis, OR

Jay Garner
U.S. Environmental Protection Agency
Environmental Monitoring Systems Laboratory
Las Vegas, NV

Jack H. Gentile
U.S. Environmental Protection Agency
Environmental Research Laboratory
Narragansett, RI

Sarah Gerould
U.S. Geological Survey
Reston, VA

George R. Gibson, Jr.
U.S. Environmental Protection Agency
Office of Water
Washington, DC

Alden D. Hinckley
U.S. Environmental Protection Agency
Office of Policy, Planning and Evaluation
Washington, DC

Erich Hyatt
U.S. Environmental Protection Agency
Office of Research and Development
Washington, DC

Norman E. Kowal
U.S. Environmental Protection Agency
Systems Laboratory
Cincinnati, OH

Ronald B. Landy
U.S. Environmental Protection Agency
Office of Technology Transfer and Regulatory Support
Washington, DC

Foster L. Mayer
U.S. Environmental Protection Agency
Environmental Research Laboratory
Gulf Breeze, FL

Melissa McCullough
U.S. Environmental Protection Agency
Office of Air Quality Planning and Standards
Washington, DC

J. Gareth Pearson
U.S. Environmental Protection Agency
Environmental Monitoring Systems Laboratory
Las Vegas, NV

Ronald Preston
U.S. Environmental Protection Agency
Region 3
Philadelphia, PA

John Schneider
U.S. Environmental Protection Agency
Region 5
Chicago, IL

Harvey Simon
U.S. Environmental Protection Agency
Region 2
New York, NY

Michael W. Slimak
U.S. Environmental Protection Agency
Office of Environmental Processes and Effects Research
Washington, DC

Q. Jerry Stober
U.S. Environmental Protection Agency
Region 4
Atlanta, GA

Greg R. Susanke
U.S. Environmental Protection Agency
Office of Pesticide Programs
Washington, DC

Leslie W. Touart
U.S. Environmental Protection Agency
Office of Pesticide Programs
Washington, DC

Michael E. Troyer
U.S. Environmental Protection Agency
Office of Technology Transfer and Regulatory Support
Washington, DC

Douglas J. Urban
U.S. Environmental Protection Agency
Office of Pesticide Programs
Washington, DC

Maurice G. Zeeman
U.S. Environmental Protection Agency
Office of Toxic Substances
Washington, DC

Peer Review Workshop Participants

William J. Adams
ABC Laboratories
Columbia, MO

Lawrence W. Barnthouse
Oak Ridge National Laboratory
Oak Ridge, TN

John Bascietto
U.S. Department of Energy
Washington, DC

Raymond Beaumier
Ohio Environmental Protection Agency
Columbus, OH

Harold Bergman
University of Wyoming
Laramie, NY

Nigel Blakeley
Washington Department of Ecology
Olympia, WA

James Falco
Battelle Pacific Northwest Laboratory
Richland, WA

James A. Fava
Roy F. Weston, Inc.
West Chester, PA

Alyce Fritz
National Oceanic and Atmospheric
Administration
Seattle, WA

James W. Gillett
Cornell University
Ithaca, NY

Michael C. Harrass
Food and Drug Administration
Washington, DC

Mark Harwell
University of Miami
Miami, FL

Ronald J. Kendall
Clemson University
Pendleton, SC

Wayne G. Landis
Western Washington University
Bellingham, WA

Ralph Portier
Louisiana State University
Baton Rouge, LA

Kenneth Reckhow
Duke University
Durham, NC

John H. Rodgers
University of Mississippi
University, MS

Peter Van Voris
Battelle Pacific Northwest Laboratory
Richland, WA

James Weinberg
Woods Hole Oceanographic Institution
Woods Hole, MA

Randall S. Wentsel
U.S. Army Chemical Research, Development
and Engineering Center
Aberdeen Proving Ground, MD

EXECUTIVE SUMMARY

This report, "Framework for Ecological Risk Assessment", is the first step in a long-term effort to develop risk assessment guidelines for ecological effects. Its primary purpose is to offer a simple, flexible structure for conducting and evaluating ecological risk assessment within EPA. Although the Framework Report will serve as a foundation for development of future subject-specific guidelines, it is neither a procedural guide nor a regulatory requirement within EPA and is expected to evolve with experience. The Framework Report is intended to foster consistent approaches to ecological risk assessment within EPA, identify key issues, and define terms used in these assessments.

Ecological risk assessments evaluate ecological effects caused by human activities such as draining of wetlands or release of chemicals. The term "stressor" is used here to describe any chemical, physical, or biological entity that can induce adverse effects on individuals, populations, communities, or ecosystems. Thus, the ecological risk assessment process must be flexible while providing a logical and scientific structure to accommodate a broad array of stressors.

The framework is conceptually similar to the approach used for human health risk assessment, but it is distinctive in its emphasis in three areas. First, ecological risk assessment can consider effects beyond those on individuals of a single species and may examine a population, community, or ecosystem. Second, there is no single set of ecological values to be protected that can be generally applied. Rather, these values are selected from a number of possibilities based on both scientific and policy considerations. Finally, there is an increasing awareness of the need for ecological risk assessments to consider nonchemical as well as chemical stressors.

The framework consists of three major phases: (1) problem formulation, (2) analysis, and (3) risk characterization. Problem formulation is a planning and scoping process that establishes the goals, breadth, and focus of the risk assessment. Its end product is a conceptual model that identifies the environmental values to be protected (the assessment endpoints), the data needed, and the analyses to be used.

The analysis phase develops profiles of environmental exposure and the effects of the stressor. The exposure profile characterizes the ecosystems in which the stressor may occur as well as the biota that may be exposed. It also describes the magnitude and spatial and temporal patterns of exposure. The ecological effects profile summarizes data on the effects of the stressor and relates them to the assessment endpoints.

Risk characterization integrates the exposure and effects profiles. Risks can be estimated using a variety of techniques including comparing individual exposure and effects values, comparing the distributions of exposure and effects, or using simulation models. Risk can be expressed as a qualitative or quantitative estimate, depending on available data. In this step, the assessor also:

- describes the risks in terms of the assessment endpoint;
- discusses the ecological significance of the effects;
- summarizes overall confidence in the assessment; and
- discusses the results with the risk manager.

The framework also recognizes several activities that are integral to, but separate from, the risk assessment process as defined in this report. For example, discussions between the risk assessor and risk manager are important. At the initiation of the risk assessment, the risk manager can help ensure that the risk assessment will ultimately provide information that is relevant to making decisions on the issues under consideration, while the risk assessor can ensure that the risk assessment addresses all relevant ecological concerns. Similar discussions of the results of the risk assessment are important to provide the risk manager with a full and complete understanding of the assessment's conclusions, assumptions, and limitations.

Other important companion activities to ecological risk assessment include data acquisition and verification and monitoring studies. New data are frequently required to conduct analyses that are performed during the risk assessment. Data from verification studies can be used to validate the predictions of a specific risk assessment as well as to evaluate the usefulness of the principles set forth in the Framework. Ecological effects or exposure monitoring can aid in the verification process and suggest additional data, methods, or analyses that could improve future risk assessments.

1. INTRODUCTION

Public, private, and government sectors of society are increasingly aware of ecological issues including global climate change, habitat loss, acid deposition, a decrease in biological diversity, and the ecological impacts of xenobiotic compounds such as pesticides and toxic chemicals. To help assess these and other ecological problems, the U.S. Environmental Protection Agency (EPA) has developed this report, "Framework for Ecological Risk Assessment", which describes the basic elements, or framework, of a process for evaluating scientific information on the adverse effects of stressors on the environment. The term "stressor" is defined here as any physical, chemical, or biological entity that can induce an adverse effect (see box[1]). Adverse ecological effects encompass a wide range of disturbances ranging from mortality in an individual organism to a loss in ecosystem function.

This introductory section describes the purpose, scope, and intended audience for this report; discusses the definition and application of ecological risk assessment; outlines the basic elements of the proposed framework; and describes the organization of this report.

> **Physical and Chemical Stressors as a Focus of the Framework**
>
> This report does not discuss accidentally or deliberately introduced species, genetically engineered organisms, or organisms used to control horticultural or agricultural pests. While the general principles described in the framework may be helpful in addressing risks associated with these organisms, the capacity of such organisms for reproduction and biological interaction introduces additional considerations that are not addressed in this document.

1.1. Purpose and Scope of the Framework Report

An understanding of the finite purpose and scope of this Framework Report is important. EPA, other regulatory agencies, and other organizations need detailed, comprehensive guidance on methods for evaluating ecological risk. However, in discussing tentative plans for developing such guidance with expert consultants (U.S. EPA, 1991; U.S. EPA, in press-a), EPA was advised to first develop a simple framework as a foundation or blueprint for later comprehensive guidance on ecological risk assessment.

With this background, the framework (see section 1.4) has two simple purposes, one immediate and one longer term. As a broad outline of the assessment process, the framework offers a basic structure and starting principles for EPA's ecological risk assessments. The process described by the framework provides wide latitude for planning and conducting individual risk assessments in many diverse situations, each based on the common principles discussed in the framework. The process also will help foster a consistent EPA approach for conducting and evaluating ecological risk assessments, identify key issues, and provide operational definitions for terms used in ecological risk assessments.

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[1]The boxes used throughout this document serve several purposes. Some boxes provide additional background and rationale for terms, whereas other boxes expand on concepts described in the text. The boxes at the end of each chapter highlight issues that are integral components of the risk assessment process but require more research, analysis, and debate. Further discussion of these issues is reserved for later guidelines.

In addition, the framework offers basic principles around which long-term guidelines for ecological risk assessment can be organized. With this in mind, this report does not provide substantive guidance on factors that are integral to the risk assessment process such as analytical methods, techniques for analyzing and interpreting data, or guidance on factors influencing policy. Rather, on the basis of EPA experience and the recommendations of peer reviewers, EPA has reserved discussion of these important aspects of any risk assessment for future guidelines, which will be based on the process described in this report.

1.2. Intended Audience

The framework is primarily intended for EPA risk assessors, EPA risk managers, and other persons who either perform work under EPA contract or sponsorship or are subject to EPA regulations. The terminology and concepts described here also may be of assistance to other Federal, State, and local agencies as well as to members of the general public who are interested in ecological issues.

1.3. Definition and Applications of Ecological Risk Assessment

Ecological risk assessment is defined as a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. A risk does not exist unless (1) the stressor has the inherent ability to cause one or more adverse effects and (2) it co-occurs with or contacts an ecological component (i.e., organisms, populations, communities, or ecosystems) long enough and at a sufficient intensity to elicit the identified adverse effect. Ecological risk assessment may evaluate one or many stressors and ecological components.

Ecological risk may be expressed in a variety of ways. While some ecological risk assessments may provide true probabilistic estimates of both the adverse effect and exposure elements, others may be deterministic or even qualitative in nature. In these cases, the likelihood of adverse effects is expressed through a semiquantitative or qualitative comparison of effects and exposure.

Ecological risk assessments can help identify environmental problems, establish priorities, and provide a scientific basis for regulatory actions. The process can identify existing risks or forecast the risks of stressors not yet present in the environment. However, while ecological risk assessments can play an important role in identifying and resolving environmental problems, risk assessments are not a solution for addressing all environmental problems, nor are they always a prerequisite for environmental management. Many environmental matters such as the protection of habitats and endangered species are compelling enough that there may not be enough time or data to do a risk assessment. In such cases, professional judgment and the mandates of a particular statute will be the driving forces in making decisions.

1.4. Ecological Risk Assessment Framework

The distinctive nature of the framework results primarily from three differences in emphasis relative to previous risk assessment approaches. First, ecological risk assessment can consider effects beyond those on individuals of a single species and may examine population, community, or ecosystem impacts. Second, there is no one set of assessment endpoints (environmental values to be protected) that can be generally applied. Rather, assessment endpoints are selected from a very large number of possibilities based on both scientific and policy considerations. Finally, a comprehensive approach to ecological risk assessment may go beyond the traditional emphasis on chemical effects to consider the possible effects of nonchemical stressors.

The ecological risk assessment framework is shown in figure 1. The risk assessment process is based on two major elements: characterization of exposure and characterization of ecological effects. Although these two elements are most prominent during the analysis phase, aspects of both exposure and effects also are considered during problem formulation, as illustrated by the arrows in the diagram. The arrows also flow to risk characterization, where the exposure and effects elements are integrated to estimate risk. The framework is conceptually similar to the National Research Council (NRC) paradigm for human health risk assessments (NRC, 1983).

The first phase of the framework is problem formulation. Problem formulation includes a preliminary characterization of exposure and effects, as well as examination of scientific data and data needs, policy and regulatory issues, and site-specific factors to define the feasibility, scope, and objectives for the ecological risk assessment. The level of detail and the information that will be needed to complete the assessment also are determined. This systematic planning phase is proposed because ecological risk assessments often address the risks of stressors to many species as well as risks to communities and ecosystems. In addition, there may be many ways a stressor can elicit adverse effects (e.g., direct effects on mortality and growth and indirect effects such as decreased food supply). Problem formulation provides an early identification of key factors to be considered, which in turn will produce a more scientifically sound risk assessment.

Relationship of the Framework to a Paradigm for Human Health Risk Assessment

In 1983, NRC published a paradigm that has been used in the development of EPA's human health risk assessment guidelines. The paradigm has four phases: hazard identification, dose-response assessment, exposure assessment, and risk characterization (NRC, 1983). Although the framework's problem formulation phase is not explicitly identified in the NRC paradigm, comparable planning issues are addressed in practice at the beginning of all EPA risk assessments. In the framework's analysis phase, characterization of exposure is analogous to exposure assessment, while characterization of ecological effects includes aspects of both hazard identification and dose-response assessment. (The framework uses the term "stressor response" rather than "dose response" because many Agency programs must address stressors other than chemicals, and dose has been used only for chemicals.) Risk characterization is a similar process in both the framework and the NRC paradigm.

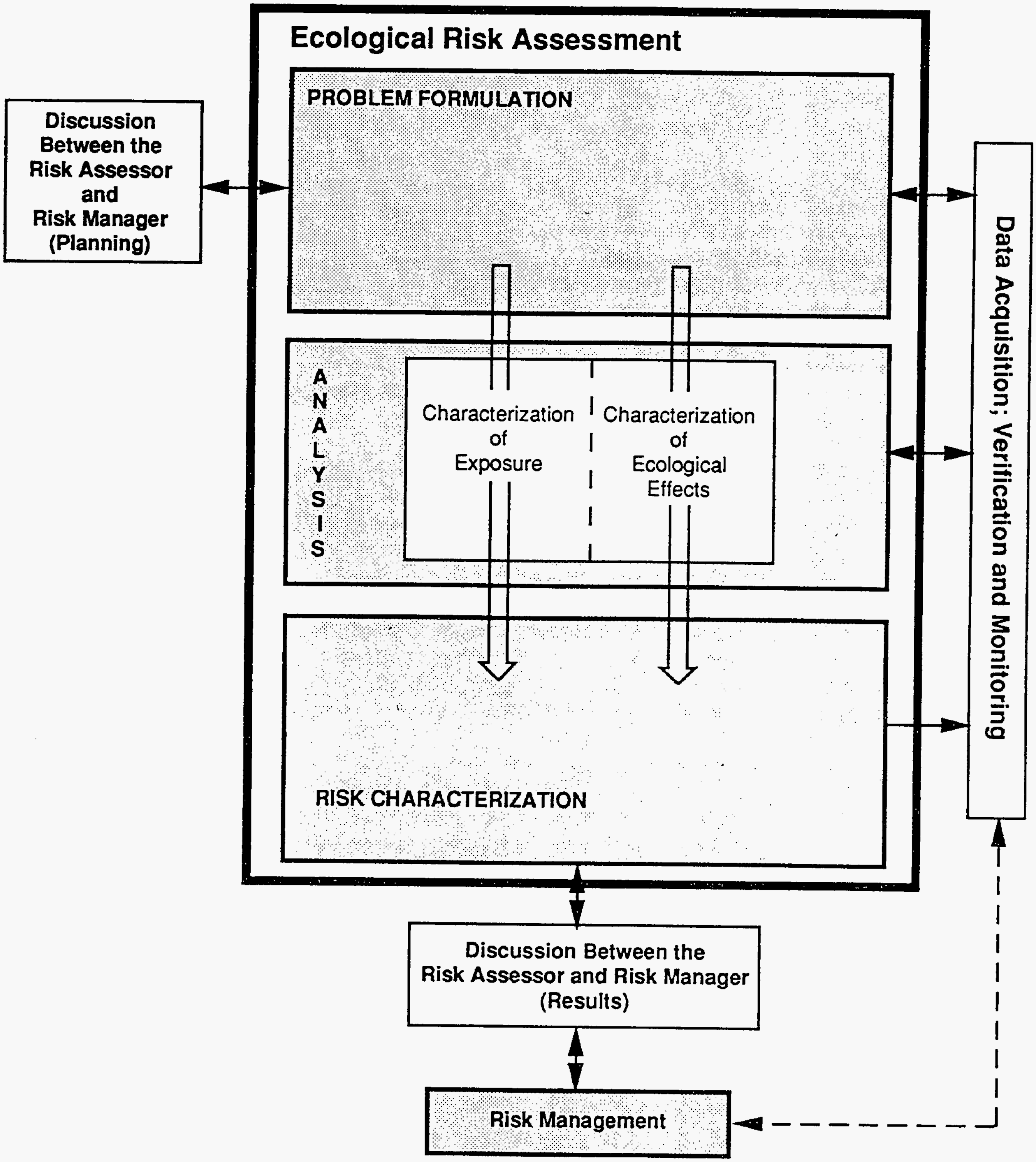

Figure 1. Framework for Ecological Risk Assessment

The second phase of the framework is termed analysis and consists of two activities, characterization of exposure and characterization of ecological effects. The purpose of characterization of exposure is to predict or measure the spatial and temporal distribution of a stressor and its co-occurrence or contact with the ecological components of concern, while the purpose of characterization of ecological effects is to identify and quantify the adverse effects elicited by a stressor and, to the extent possible, to evaluate cause-and-effect relationships.

The third phase of the framework is risk characterization. Risk characterization uses the results of the exposure and ecological effects analyses to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. It includes a summary of the assumptions used, the scientific uncertainties, and the strengths and weaknesses of the analyses. In addition, the ecological significance of the risks is discussed with consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery. The purpose is to provide a complete picture of the analysis and results.

In addition to showing the three phases of the framework, figure 1 illustrates the need for discussions between the risk assessor and risk manager. At the initiation of the risk assessment, the risk manager can help ensure that the risk assessment will ultimately provide information that is relevant to making decisions on the issues under consideration, while the risk assessor can ensure that the risk assessment addresses all relevant ecological concerns. Similar discussions of the results of the risk assessment are important to provide the risk manager with a full and complete understanding of the assessment's conclusions, assumptions, and limitations.

Figure 1 also indicates a role for verification and monitoring in the framework. Verification can include validation of the ecological risk assessment process as well as confirmation of specific predictions made during a risk assessment. Monitoring can aid in the verification process and may identify additional topics for risk assessment. Verification and monitoring can help determine the overall effectiveness of the framework approach, provide necessary feedback concerning the need for future modifications of the framework,

Use of the Term "Exposure"

Some reviewers of earlier drafts of this interim framework proposed that the term "exposure",--which, as used in human health risk assessment, generally refers to chemical stressors,--not be used for the nonchemical stressors that can affect a variety of ecological components. Other terms, including "characterization of stress", have been suggested. At this time, EPA prefers exposure, partly because characterization of stress does not convey the important concept of the co-occurrence and interaction of the stressor with an ecological component as well as exposure does.

Characterization of Ecological Effects Used Instead of Hazard Assessment

The framework uses characterization of ecological effects rather than hazard assessment for two reasons. First, the term "hazard" can be ambiguous, because it has been used in the past to mean either evaluating the intrinsic effects of a stressor (U.S. EPA, 1979) or defining a margin of safety or quotient by comparing a toxicological endpoint of interest with an estimate of exposure concentration (SETAC, 1987). Second, many reviewers believed that hazard is more relevant to chemical than to nonchemical stressors.

help evaluate the effectiveness and practicality of policy decisions, and point out the need for new or improved scientific techniques (U.S. EPA, in press-a).

The interaction between data acquisition and ecological risk assessment is also shown in figure 1. In this report, a distinction is made between data acquisition (which is outside of the risk assessment process) and data analysis (which is an integral part of an ecological risk assessment). In the problem formulation and analysis phases, the risk assessor may identify the need for additional data to complete an analysis. At this point, the risk assessment stops until the necessary data are acquired. When a need for additional data is recognized in risk characterization, new information generally is used in the analysis or problem formulation phases. The distinction between data acquisition and analysis generally is maintained in all of EPA's risk assessment guidelines; guidance on data acquisition procedures are provided in documents prepared for specific EPA programs.

The interactions between data acquisition and ecological risk assessment often result in an iterative process. For example, data used during the analysis phase may be collected in tiers of increasing complexity and cost. A decision to advance from one tier to the next is based on decision triggers set at certain levels of effect or exposure. Iterations of the entire risk assessment process also may occur. For example, a screening-level risk assessment may be performed using readily available data and conservative assumptions; depending on the results, more data then may be collected to support a more rigorous assessment.

1.5. The Importance of Professional Judgment

Ecological risk assessments, like human health risk assessments, are based on scientific data that are frequently difficult and complex, conflicting or ambiguous, or incomplete. Analyses of such data for risk assessment purposes depends on professional judgment based on scientific expertise. Professional judgment is necessary to:

- design and conceptualize the risk assessment;
- evaluate and select methods and models;
- determine the relevance of available data to the risk assessment;
- develop assumptions based on logic and scientific principles to fill data gaps; and
- interpret the ecological significance of predicted or observed effects.

Because professional judgment is so important, specialized knowledge and experience in the various phases of ecological risk assessment is required. Thus, an interactive multidisciplinary team that includes biologists and ecologists is a prerequisite for a successful ecological risk assessment.

1.6. Organization

The next three sections of this report are arranged to follow the framework sequentially. Section 2 describes problem formulation; this section is particularly important for assessors to consider when specific assessment endpoints are not determined a priori by statute or other authority. Sections 3 and 4 discuss analysis and risk characterization, respectively. Section 5 defines the terms used in this report, and section 6 provides literature references. The lists of ecological risk assessment issues at the end of sections 1 through 4 highlight areas for further discussion and research. EPA believes that these issues will require special attention in developing ecological risk assessment guidelines.

Additional Issues Related to the Framework

- o Use of the framework for evaluating risks associated with biological stressors.
- o Use of the term exposure (versus characterization of stress) for both chemical and nonchemical stressors.
- o Use of the term characterization of ecological effects rather than hazard assessment.

2. PROBLEM FORMULATION

Problem formulation is the first phase of ecological risk assessment and establishes the goals, breadth, and focus of the assessment. It is a systematic planning step that identifies the major factors to be considered in a particular assessment, and it is linked to the regulatory and policy context of the assessment.

Entry into the ecological risk assessment process may be triggered by either an observed ecological effect, such as visible damage to trees in a forest, or by the identification of a stressor or activity of concern, such as the planned filling of a marsh or the manufacture of a new chemical. The problem formulation process (figure 2) then begins with the initial stages of characterizing exposure and ecological effects, including evaluating the stressor characteristics, the ecosystem potentially at risk, and the ecological effects expected or observed. Next, the assessment and measurement endpoints are identified. (Measurement endpoints are ecological characteristics that can be related to the assessment endpoint.) The outcome of problem formulation is a conceptual model that describes how a given stressor might affect the ecological components in the environment. The conceptual model also describes the relationships among the assessment and measurement endpoints, the data required, and the methodologies that will be used to analyze the data. The conceptual model serves as input to the analysis phase of the assessment.

2.1. Discussion Between the Risk Assessor and Risk Manager (Planning)

To be meaningful and effective, ecological risk assessments must be relevant to regulatory needs and public concerns as well as scientifically valid. Although risk assessment and risk management are distinct processes, establishing a two-way dialogue between risk assessors and risk managers during the problem formulation phase can be a constructive means of achieving both societal and scientific goals. By bringing the management perspective to the discussion, risk managers charged with protecting societal values can ensure that the risk assessment will provide relevant information to making decisions on the issue under consideration. By bringing scientific knowledge to the discussion, the ecological risk assessor ensures that the assessment addresses all important ecological concerns. Both perspectives are necessary to appropriately utilize resources to produce scientifically sound risk assessments that are relevant to management decisions and public concerns.

2.2. Stressor Characteristics, Ecosystem Potentially at Risk, and Ecological Effects

The initial steps in problem formulation are the identification and preliminary characterization of stressors, the ecosystem potentially at risk, and ecological effects. Performing this analysis is an interactive process that contributes to both the selection of assessment and measurement endpoints and the development of a conceptual model.

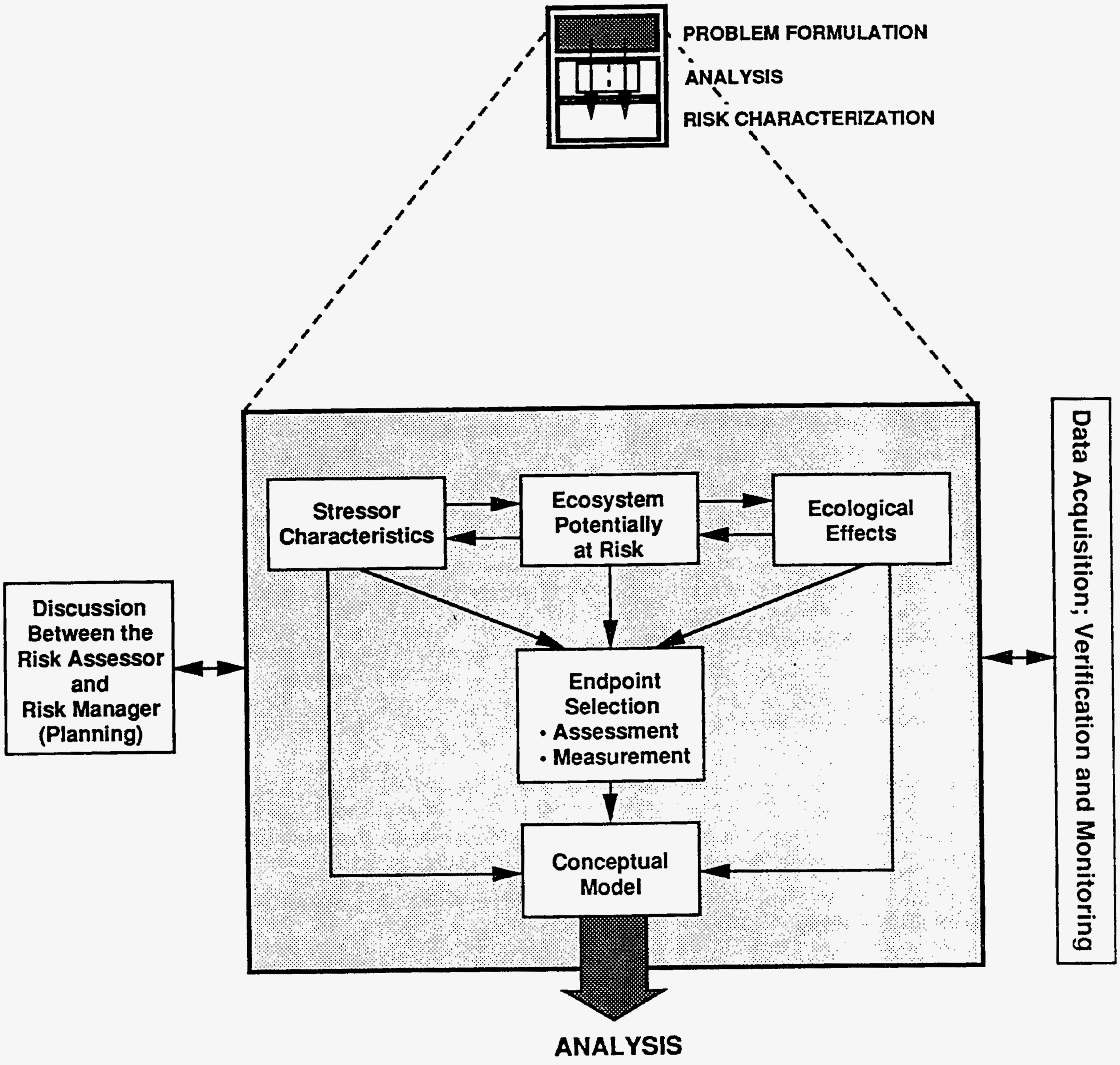

Figure 2. Problem Formulation

2.2.1. Stressor Characteristics

The determination of stressor characteristics begins with the identification of potential chemical or physical stressors. Chemical stressors include a variety of inorganic and organic substances. Some chemicals may result in secondary stressors, as in the case of stratospheric ozone depletion caused by chlorofluorocarbons that could result in increased exposures to ultraviolet radiation. Physical stressors include extremes of natural conditions (e.g., temperature and hydrologic changes) and habitat alteration or destruction. Stressors that may result from management practices, such as harvesting of fishery or forest resources, also may be considered. Example stressor characteristics are summarized in the box below. Gathering information on the characteristics of a stressor helps define the ecosystems potentially at risk from the stressor as well as the ecological effects that may result.

2.2.2. Ecosystem Potentially at Risk

The ecosystem within which effects occur provides the ecological context for the assessment. Knowledge of the ecosystem potentially at risk can help identify ecological components that may be affected and stressor-ecosystem interactions relevant to developing exposure scenarios. The approach to identifying the ecosystem potentially at risk from a stressor depends in part on how the risk assessment was initiated. If a stressor first was identified, information on the spatial and temporal distribution patterns of the stressor can be helpful in identifying ecosystems potentially at risk. Similarly, if the risk assessment is initiated by observing effects, these effects can directly indicate ecosystems or ecological components that may be considered in the assessment.

Example Stressor Characteristics

Type

Chemical or physical

Intensity

Concentration or magnitude

Duration

Short or long term

Frequency

Single event, episodic, or continuous

Timing

Occurrence relative to biological cycles

Scale

Spatial heterogeneity and extent

A wide range of ecosystem properties may be considered during problem formulation. These properties include aspects of the abiotic environment (such as climatic conditions and soil or sediment properties), ecosystem structure (including the types and abundances of different species and their trophic level relationships), and ecosystem function (such as the ecosystem energy source, pathways of energy utilization, and nutrient processing) (U.S. EPA, in press-b). In addition, knowledge of the types and patterns of historical disturbances may be helpful in predicting ecological responses to stressors.

The need to evaluate spatial and temporal distribution and variation is inherent in many of these example characteristics. Such information is especially useful for determining potential exposure, that is, where there is co-occurrence of or contact between the stressor and ecological components.

2.2.3. Ecological Effects

Ecological effects data may come from a variety of sources. Relevant sources of information include field observations (e.g., fish or bird kills, changes in aquatic community structure), field tests (e.g., microcosm or mesocosm tests), laboratory tests (e.g., single species or microcosm tests), and chemical structure-activity relationships. Available information on ecological effects can help focus the assessment on specific stressors and on ecological components that should be evaluated.

Many factors can influence the utility of available ecological effects data for problem formulation. For example, the applicability of laboratory-based tests may be affected by any extrapolations required to specific field situations, while the interpretation of field observations may be influenced by factors such as natural variability or the possible presence of stressors other than the ones that are the primary focus of the risk assessment.

2.3. Endpoint Selection

Information compiled in the first stage of problem formulation is used to help select ecologically based endpoints that are relevant to decisions made about protecting the environment. An endpoint is a characteristic of an ecological component (e.g., increased mortality in fish) that may be affected by exposure to a stressor (Suter, 1990a). Two types of endpoints are distinguished in this report. Assessment endpoints are explicit expressions of the actual environmental value that is to be protected. Measurement endpoints are measurable responses to a stressor that are related to the valued characteristics chosen as the assessment endpoints (Suter, 1990a).

> **Endpoint Terminology**
>
> Several reviewers have suggested using the term "indicator" in place of "measurement endpoint". At this time, measurement endpoint is preferred because it has a specific meaning (a characteristic of an ecological system that can be related to an assessment endpoint), whereas indicator can have several different meanings. For example, indicator has been used at EPA to mean (1) measures of administrative accomplishments (e.g., number of permits issued), (2) measures of exposure (e.g., chemical levels in sediments), or (3) measures of ecosystem integrity. These indicators cannot always be related to an assessment endpoint.

Assessment endpoints are the ultimate focus in risk characterization and link the measurement endpoints to the risk management process (e.g., policy goals). When an assessment endpoint can be directly measured, the measurement and assessment endpoints are the same. In most cases, however, the assessment endpoint cannot be directly measured, so a measurement endpoint (or a suite of measurement endpoints) is selected that can be related, either qualitatively or quantitatively, to the assessment endpoint. For example, a decline in a sport fish population (the assessment endpoint) may be evaluated using laboratory studies on the mortality of surrogate species, such as the fathead minnow (the measurement endpoint). Sound professional judgment is necessary for proper assessment and measurement endpoint selection, and it is important that both the selection rationale and the linkages between measurement endpoints, assessment endpoints, and policy goals be clearly stated.

Assessment and measurement endpoints may involve ecological components from any level of biological organization, ranging from individual organisms to the ecosystem itself. In general, the use of a suite of assessment and measurement endpoints at different organizational levels can build greater confidence in the conclusions of the risk assessment and ensure that all important endpoints are evaluated. In some situations, measurement endpoints at one level of organization may be related to an assessment endpoint at a higher level. For example, measurement endpoints at the individual level (e.g., mortality, reproduction, and growth) could be used in a model to predict effects on an assessment endpoint at the population level (e.g., viability of a trout population in a stream).

General considerations for selecting assessment and measurement endpoints are detailed in the following boxes. More detailed discussions of endpoints and selection criteria can be found in Suter (1989, 1990a), Kelly and Harwell (1990), U.S. Department of the Interior (1987), and U.S. EPA (1990a).

Considerations in Selecting Assessment Endpoints

Ecological Relevance

Ecologically relevant endpoints reflect important characteristics of the system and are functionally related to other endpoints. Selection of ecologically relevant endpoints requires some understanding of the structure and function of the ecosystem potentially at risk. For example, an assessment endpoint could focus on changes in a species known to have a controlling influence on the abundance and distribution of many other species in its community. Changes at higher levels of organization may be significant because of their potential for causing major effects at lower organizational levels.

Policy Goals and Societal Values

Good communication between the risk assessor and risk manager is important to ensure that ecologically relevant assessment endpoints reflect policy goals and societal values. Societal concerns can range from protection of endangered or commercially or recreationally important species to preservation of ecosystem attributes for functional reasons (e.g., flood water retention by wetlands) or aesthetic reasons (e.g., visibility in the Grand Canyon).

Susceptibility to the Stressor

Ideally, an assessment endpoint would be likely to be both affected by exposure to a stressor and sensitive to the specific type of effects caused by the stressor. For example, if a chemical is known to bioaccumulate and is suspected of causing eggshell thinning, an appropriate assessment endpoint might be raptor population viability.

Considerations in Selecting Measurement Endpoints

Relevance to an Assessment Endpoint

When an assessment endpoint cannot be directly measured, measurement endpoints are identified that are correlated with or can be used to infer or predict changes in the assessment endpoint.

Consideration of Indirect Effects

Indirect effects occur when a stressor acts on elements of the ecosystem that are required by the ecological component of concern. For example, if the assessment endpoint is the population viability of trout, measurement endpoints could evaluate possible stressor effects on trout prey species or habitat requirements.

Sensitivity and Response Time

Rapidly responding measurement endpoints may be useful in providing early warnings of ecological effects, and measurement endpoints also may be selected because they are sensitive surrogates of the assessment endpoint. In many cases, measurement endpoints at lower levels of biological organization may be more sensitive than those at higher levels. However, because of compensatory mechanisms and other factors, a change in a measurement endpoint at a lower organizational level (e.g., a biochemical alteration) may not necessarily be reflected in changes at a higher level (e.g., population effects).

Signal-to-Noise Ratio

If a measurement endpoint is highly variable, the possibility of detecting stressor-related effects may be greatly reduced even if the endpoint is sensitive to the stressor.

Consistency With Assessment Endpoint Exposure Scenarios

The ecological component of the measurement endpoint should be exposed by similar routes and at similar or greater stressor levels as the ecological component of the assessment endpoint.

Diagnostic Ability

Measurement endpoints that are unique or specific responses to a stressor may be very useful in diagnosing the presence or effects of a stressor. For example, measurement of acetylcholinesterase inhibition may be useful for demonstrating responses to certain types of pesticides.

Practicality Issues

Ideal measurement endpoints are cost effective and easily measured. The availability of a large database for a measurement endpoint is desirable to facilitate comparisons and develop models.

2.4. The Conceptual Model

The major focus of the conceptual model (figure 2) is the development of a series of working hypotheses regarding how the stressor might affect ecological components of the natural environment (NRC, 1986). The conceptual model also includes descriptions of the ecosystem potentially at risk and the relationship between measurement and assessment endpoints.

During conceptual model development, a preliminary analysis of the ecosystem, stressor characteristics, and ecological effects is used to define possible exposure scenarios. Exposure scenarios consist of a qualitative description of how the various ecological components co-occur with or contact the stressor. Each scenario is defined in terms of the stressor, the type of biological system and principal ecological components, how the stressor will contact or interact with the system, and the spatial and temporal scales.

For chemical stressors, the exposure scenario usually involves consideration of sources, environmental transport, partitioning of the chemical among various environmental media, chemical/biological transformation or speciation processes, and identification of potential routes of exposure (e.g., ingestion). For nonchemical stressors such as water level or temperature changes or physical disturbance, the exposure scenario describes the ecological components exposed and the general temporal and spatial patterns of their co-occurrence with the stressor. For example, for habitat alterations, the exposure scenario may describe the extent and distributional pattern of disturbance, the populations residing within or using the disturbed areas, and the spatial relationship of the disturbed area to undisturbed areas.

Although many hypotheses may be generated during problem formulation, only those that are considered most likely to contribute to risk are selected for further evaluation in the analysis phase. For these hypotheses, the conceptual model describes the approach that will be used for the analysis phase and the types of data and analytical tools that will be needed. It is important that hypotheses that are not carried forward in the assessment because of data gaps be acknowledged when uncertainty is addressed in risk characterization. Professional judgment is needed to select the most appropriate risk hypotheses, and it is important to document the selection rationale.

Additional Issues in Problem Formulation

o Role of risk management concerns in establishing assessment endpoints.

Although it is important to consider risk management concerns when assessment endpoints are selected, there is still uncertainty as to how these inputs should influence the goals of the risk assessment, the ecological components to be protected, and the level of protection required.

o Identifying specific assessment and measurement endpoints for different stressors and ecosystems.

3. ANALYSIS PHASE

The analysis phase of ecological risk assessment (figure 3) consists of the technical evaluation of data on the potential effects and exposure of the stressor. The analysis phase is based on the conceptual model developed during problem formulation. Although this phase consists of characterization of ecological effects and characterization of exposure, the dotted line in figure 3 illustrates that the two are performed interactively. An interaction between the two elements will ensure that the ecological effects characterized are compatible with the biota and exposure pathways identified in the exposure characterization. The output of ecological effects characterization and exposure characterization are summary profiles that are used in the risk characterization phase (section 4). Discussion of uncertainty analysis, which is an important part of the analysis phase, may be found in section 4.1.2.

Characterization of exposure and ecological effects often requires the application of statistical methods. While the discussion of specific statistical methods is beyond the scope of this document, selection of an appropriate statistical method involves both method assumptions (e.g., independence of errors, normality, equality of variances) and data set characteristics (e.g., distribution, presence of outliers or influential data). It should be noted that statistical significance does not always reflect biological significance, and profound biological changes may not be detected by statistical tests. Professional judgment often is required to evaluate the relationship between statistical and biological significance.

3.1. Characterization of Exposure

Characterization of exposure (half of the analysis phase shown in figure 3) evaluates the interaction of the stressor with the ecological component. Exposure can be expressed as co-occurrence or contact depending on the stressor and the ecological component involved. An exposure profile is developed that quantifies the magnitude and spatial and temporal distributions of exposure for the scenarios developed during problem formulation and serves as input to the risk characterization.

3.1.1. Stressor Characterization: Distribution or Pattern of Change

Stressor characterization involves determining the stressor's distribution or pattern of change. Many techniques can be applied to assist in this stressor characterization process. For chemical stressors, a combination of modeling and monitoring data often is used. Available monitoring data may include measures of releases into the environment and media concentrations over space and time. Fate and transport models often are used that rely on physical and chemical characteristics of the chemical coupled with the characteristics of the ecosystem. For nonchemical stressors such as physical alterations or harvesting, the pattern of change may depend on resource management or land-use practices. Depending on the scale of the disturbance, the data for stressor characterization can be provided by a variety of techniques, including ground reconnaissance, aerial photographs, or satellite imagery.

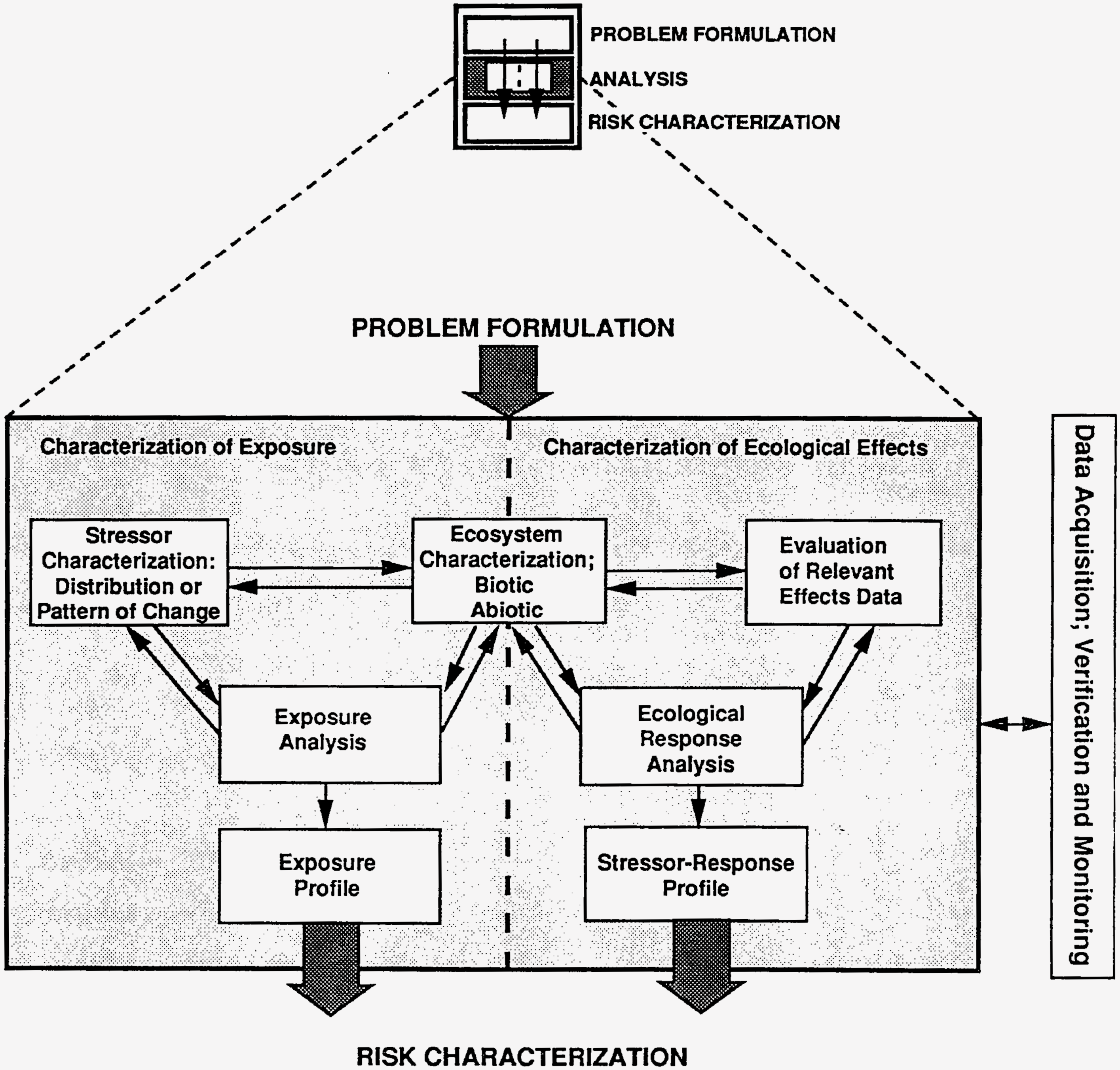

Figure 3. Analysis

During stressor characterization, one considers not only the primary stressor but also secondary stressors that can arise as a result of various processes. For example, removal of riparian (stream-side) vegetation not only alters habitat structure directly, but can have additional ramifications such as increased siltation and temperature rise. For chemicals, secondary stressors can be produced by a range of environmental fate processes.

The timing of the stressor's interaction with the biological system is another important consideration. If the stressor is episodic in nature, different species and life stages may be affected. In addition, the ultimate distribution of a stressor is rarely homogeneous; it is important to quantify such heterogeneity whenever possible.

3.1.2. Ecosystem Characterization

During ecosystem characterization, the ecological context of the assessment is further analyzed. In particular, the spatial and temporal distributions of the ecological component are characterized, and the ecosystem attributes that influence the distribution and nature of the stressor are considered.

Characteristics of the ecosystem can greatly modify the ultimate nature and distribution of the stressor. Chemical stressors can be modified through biotransformation by microbial communities or through other environmental fate processes, such as photolysis, hydrolysis, and sorption. The bioavailability of chemical stressors also can be affected by the environment, which in turn influences the exposure of ecological components.

Physical stressors can be modified by the ecosystem as well. For example, siltation in streams depends not only on sediment volume, but on flow regime and physical stream characteristics. Similarly, nearby wetlands and levees influence water behavior during flood events.

The spatial and temporal distributions of ecological components also are considered in ecosystem characterization. Characteristics of ecological components that influence their exposure to the stressor are evaluated, including habitat needs, food preferences, reproductive cycles, and seasonal activities such as migration and selective use of resources. Spatial and temporal variations in the distribution of the ecological component (e.g., sediment invertebrate distribution) may complicate evaluations of exposure. When available, species-specific information about activity patterns, abundance, and life histories can be very useful in evaluating spatial and temporal distributions.

Another important consideration is how exposure to a stressor may alter natural behavior, thereby affecting further exposure. In some cases, this may lead to enhanced exposure (e.g., increased preening by birds after aerial pesticide spraying), while in other situations initial exposure may lead to avoidance of contaminated locations or food sources (e.g., avoidance of certain waste effluents or physically altered spawning beds by some fish species).

3.1.3. Exposure Analyses

The next step is to combine the spatial and temporal distributions of both the ecological component and the stressor to evaluate exposure. In the case of physical alterations of communities and ecosystems, exposure can be expressed broadly as co-occurrence. Exposure analyses of individuals often focus on actual contact with the stressor, because organisms may not contact all of the stressors present in an area. For chemical stressors, the analyses may focus further on the amount of chemical that is bioavailable, that is, available for uptake by the organism. Some chemical exposure analyses also follow the chemical within the organism's body and estimate the amount that reaches the target organ. The focus of the analyses will depend on the stressors being evaluated and the assessment and measurement endpoints.

The temporal and spatial scales used to evaluate the stressor need to be compatible with the characteristics of the ecological component of interest. A temporal scale may encompass the lifespan of a species, a particular life stage, or a particular cycle, for example, the long-term succession of a forest community. A spatial scale may encompass a forest, a lake, a watershed, or an entire region. Stressor timing relative to organism life stage and activity patterns can greatly influence the occurrence of adverse effects. Even short-term events may be significant if they coincide with critical life stages. Periods of reproductive activity may be especially important, because early life stages often are more sensitive to stressors, and adults also may be more vulnerable at this time.

The most common approach to exposure analysis is to measure concentrations or amounts of a stressor and combine them with assumptions about co-occurrence, contact, or uptake. For example, exposure of aquatic organisms to chemicals often is expressed simply as concentration in the water column; aquatic organisms are assumed to contact the chemical. Similarly, exposures of organisms to habitat alteration often is expressed as hectares of habitat altered; organisms that utilize the habitat are assumed to co-occur with the alteration. Stressor measurements can also be combined with quantitative parameters describing the frequency and magnitude of contact. For example, concentrations of chemicals in food items can be combined with ingestion rates to estimate dietary exposure of organisms.

In some situations, the stressor can be measured at the actual point of contact while exposure occurs. An example is the use of food collected from the mouths of nestling birds to evaluate exposure to pesticides through contaminated food (Kendall, 1991). Although such point-of-contact measurements can be difficult to obtain, they reduce the need for assumptions about the frequency and magnitude of contact.

Patterns of exposure can be described using models that combine abiotic ecosystem attributes, stressor properties, and ecological component characteristics. Model selection is based on the model's suitability for the ecosystem or component of interest, the availability of the requisite data, and the study objectives. Model choices range from simple, screening-level procedures that require a minimum of data to more sophisticated methods that describe processes in more detail but require a considerable amount of data.

Another approach to evaluating exposure uses chemical, biochemical, or physiological evidence (e.g., biomarkers) of a previous exposure. This approach has been used primarily for assessing chemical exposures and is particularly useful when a residue or biomarker is diagnostic of exposure to a particular chemical. These types of measurements are most useful for exposure characterization when they can be quantitatively linked to the amount of stressor originally contacted by the organism. Pharmacokinetic models are sometimes used to provide this linkage.

3.1.4. Exposure Profile

Using information obtained from the exposure analysis, the exposure profile quantifies the magnitude and spatial and temporal patterns of exposure for the scenarios developed during problem formulation and serves as input to risk characterization. The exposure profile is only effective when its results are compatible with the stressor-response profile. For example, appraisals of potential acute effects of chemical exposure may be averaged over short time periods to account for short-term pulsed stressor events. It is important that characterizations for chronic stressors account for both long-term low-level exposure and possible shorter term higher level contact that may elicit similar adverse chronic effects.

Exposure profiles can be expressed using a variety of units. For chemical stressors operating at the organism level, the usual metric is expressed in dose units (e.g., mg/kg body weight/day). For higher levels of organization (e.g., an entire ecosystem), exposure may be expressed in units of concentration/unit area/time. For physical disturbance, the exposure profile may be expressed in other terms (e.g., percentage of habitat removed or the extent of flooding/year).

An uncertainty assessment is an integral part of the characterization of exposure. In the majority of assessments, data will not be available for all aspects of the characterization of exposure, and those data that are available may be of questionable or unknown quality. Typically, the assessor will have to rely on a number of assumptions with varying degrees of uncertainty associated with each. These assumptions will be based on a combination of professional judgment, inferences based on analogy with similar chemicals and conditions and estimation techniques, all of which contribute to the overall uncertainty. It is important that the assessor characterize each of the various sources of uncertainty and carry them forward to the risk characterization so that they may be combined with a similar analysis conducted as part of the characterization of ecological effects.

3.2. Characterization of Ecological Effects

The relationship between the stressor and the assessment and measurement endpoints identified during problem formulation is analyzed in characterization of ecological effects (figure 3). The evaluation begins with the evaluation of effects data that are relevant to the stressor. During ecological response analysis, the relationship between the stressor and the ecological effects elicited is quantified, and cause-and-effect relationships are evaluated. In addition, extrapolations from measurement endpoints to assessment endpoints are conducted during this phase. The product is a stressor-response profile that quantifies and summarizes the relationship of the stressor to the assessment endpoint. The stressor-response profile is then used as input to risk characterization.

3.2.1. Evaluation of Relevant Effects Data

The type of effects data that are evaluated depends largely on the nature of the stressor and the ecological component under evaluation. Effects elicited by a stressor may range from mortality and reproductive impairment in individuals and populations to disruptions in community and ecosystem function such as primary productivity. The evaluation process relies on professional judgment, especially when few data are available or when choices among several sources of data are required. If available data are inadequate, new data may be needed before the assessment can be completed.

Data are evaluated by considering their relevance to the measurement and assessment endpoints selected during problem formulation. The analysis techniques that will be used also are considered; data that minimize the need for extrapolation are desirable. Data quality (e.g., sufficiency of replications, adherence to good laboratory practices) is another important consideration. Finally, characteristics of the ecosystem potentially at risk will influence what data will be used. Ideally, the test system reflects the physical attributes of the ecosystem and will include the ecological components and life stages examined in the risk assessment.

Data from both field observations and experiments in controlled settings can be used to evaluate ecological effects. In some cases, such as for chemicals that have yet to be manufactured, test data for the specific stressor are not available. Quantitative structure-activity relationships (QSARs) are useful in these situations (Auer et al., 1990; Clements et al., 1988; McKim et al., 1987).

Controlled laboratory and field tests (e.g., mesocosms) can provide strong causal evidence linking a stressor with a response and can also help discriminate between multiple stressors. Data from laboratory studies tend to be less variable than those from field studies, but because environmental factors are controlled, responses may differ from those in the natural environment.

Observational field studies (e.g., comparison with reference sites) provide environmental realism that laboratory studies lack, although the presence of multiple stressors and other confounding factors (e.g., habitat quality) in the natural environment can make it difficult to attribute observed effects to specific stressors. Confidence in causal relationships can be improved by carefully selecting comparable reference sites or by evaluating changes along a stressor gradient where differences in other environmental factors are minimized. It is important to consider potential confounding factors during the analysis.

3.2.2. Ecological Response Analyses

The data used in characterization of ecological effects are analyzed to quantify the stressor-response relationship and to evaluate the evidence for causality. A variety of techniques may be used, including statistical methods and mathematical modeling. In some cases, additional analyses to relate the measurement endpoint to the assessment endpoint may be necessary.

Stressor-Response Analyses

The stressor-response analysis describes the relationship between the magnitude, frequency, or duration of the stressor in an observational or experimental setting and the magnitude of response. The stressor-response analysis may focus on different aspects of the stressor-response relationship, depending on the assessment objectives, the conceptual model, and the type of data used for the analysis. Stressor-response analyses, such as those used for toxicity tests, often portray the magnitude of the stressor with respect to the magnitude of response. Other important aspects to consider include the temporal (e.g., frequency, duration, and timing) and spatial distributions of the stressor in the experimental or observational setting. For physical stressors, specific attributes of the environment after disturbance (e.g., reduced forest stand age) can be related to the response (e.g., decreased use by spotted owls) (Thomas et al., 1990).

Analyses Relating Measurement and Assessment Endpoints

Ideally, the stressor-response evaluation quantifies the relationship between the stressor and the assessment endpoint. When the assessment endpoint can be measured, this analysis is straightforward. When it cannot be measured, the relationship between the stressor and measurement endpoint is established first, then additional extrapolations, analyses, and assumptions are used to predict or infer changes in the assessment endpoint. The need for analyses relating measurement and assessment endpoints also may be identified during risk characterization, after an initial evaluation of risk.

Measurement endpoints are related to assessment endpoints using the logical structure presented in the conceptual model. In some cases, quantitative methods and models are available, but often the relationship can be described only qualitatively. Because of the lack of standard methods for many of these analyses, professional judgment is an essential component of the evaluation. It is important to clearly explain the rationale for any analyses and assumptions.

Extrapolations commonly used include those between species, between responses, from laboratory to field, and from field to field. Differences in responses among taxa depend on many factors, including physiology, metabolism, resource utilization, and life history strategy. The relationship between responses also depends on many factors, including the mechanism of action and internal distribution of the stressor within the organism. When extrapolating between different laboratory and field settings, important considerations include differences in the physical environment and organism behavior that will alter exposure, interactions with other stressors, and interactions with other ecological components.

Extrapolations and Other Analyses Relating Measurement and Assessment Endpoints

Extrapolation Between Taxa

example: from bluegill sunfish mortality to rainbow trout mortality

Extrapolation Between Responses

example: from bobwhite quail LC_{50} to bobwhite quail NOEL (no observed effect level)

Extrapolation From Laboratory to Field

example: from mouse mortality under laboratory conditions to mouse mortality in the field

Extrapolation From Field to Field

example: from reduced invertebrate community diversity in one stream to another stream

Analysis of Indirect Effects

example: relating removal of long-leaf pine to reduced populations of red-cockaded woodpecker

Analysis of Higher Organizational Levels

example: relating reduced individual fecundity to reduced population size

Analysis of Spatial and Temporal Scales

example: evaluation of the loss of a specific wetland used by migratory birds in relation to the larger scale habitat requirements of the species

Analysis of Recovery

example: relating short-term mortality to long-term depauperation

In addition to these extrapolations, an evaluation of indirect effects, other levels of organization, other temporal and spatial scales, and recovery potential may be necessary. Whether these analyses are required in a particular risk assessment will depend on the assessment endpoints identified during problem formulation.

Important factors to consider when evaluating indirect effects include interspecies interactions (e.g., competition, disease), trophic-level relationships (e.g., predation), and resource utilization. Effects on higher (or lower) organizational levels depend on the severity of the effect, the number and life stage of organisms affected, the role of those organisms in the community or ecosystem, and ecological compensatory mechanisms.

The implications of adverse effects at spatial scales beyond the immediate area of concern may be evaluated by considering ecological characteristics such as community structure and energy and nutrient dynamics. In addition, information from the characterization of exposure on the stressor's spatial distribution may be useful. Extrapolations between different temporal scales (e.g., from short-term impacts to long-term effects) may consider the stressors' distribution through time (intensity, duration, and frequency) relative to ecological dynamics (e.g., seasonal cycles, life cycle patterns).

In some cases, evaluation of long-term impacts will require consideration of ecological recovery. Ecological recovery is difficult to predict and depends on the existence of a nearby source of organisms, life history and dispersal strategies of the ecological components, and the chemical-physical environmental quality following exposure to the stressor (Cairns, 1990; Poff and Ward, 1990; Kelly and Harwell, 1990). In addition, there is some evidence to suggest that the types and frequency of natural disturbances can influence the ability of communities to recover (Schlosser, 1990).

Evaluation of Causal Evidence

Another important aspect of the ecological response analysis is to evaluate the strength of the causal association between the stressor and the measurement and assessment endpoints. This information supports and complements the stressor-response assessment and is of particular importance when the stressor-response relationship is based on field observations. Although proof of causality is not a requirement for risk assessment, an evaluation of causal evidence augments the risk assessment. Many of the concepts applied in human epidemiology can be useful for evaluating causality in observational field studies. For example, Hill (1965) suggested nine evaluation criteria for causal associations. An example of ecological causality analysis was provided by Woodman and Cowling (1987), who evaluated the causal association between air pollutants and injury to forests.

Hill's Criteria for Evaluating Causal Associations (Hill, 1965)

1. **Strength**: A high magnitude of effect is associated with exposure to the stressor.

2. **Consistency**: The association is repeatedly observed under different circumstances.

3. **Specificity**: The effect is diagnostic of a stressor.

4. **Temporality**: The stressor precedes the effect in time.

5. **Presence of a biological gradient**: A positive correlation between the stressor and response.

6. **A plausible mechanism of action.**

7. **Coherence**: The hypothesis does not conflict with knowledge of natural history and biology.

8. **Experimental evidence.**

9. **Analogy**: Similar stressors cause similar responses.

Not all of these criteria must be satisfied, but each incrementally reinforces the argument for causality. Negative evidence does not rule out a causal association but may indicate incomplete knowledge of the relationship (Rothman, 1986).

3.2.3. Stressor-Response Profile

The results of the characterization of ecological effects are summarized in a stressor-response profile that describes the stressor-response relationship, any extrapolations and additional analyses conducted, and evidence of causality (e.g., field effects data).

Ideally, the stressor-response relationship will relate the magnitude, duration, frequency, and timing of exposure in the study setting to the magnitude of effects. For practical reasons, the results of stressor-response curves are often summarized as one reference point, for instance, a 48-hour LC_{50}. Although useful, such values provide no information about the slope or shape of the stressor-response curve. When the entire curve is used, or when points on the curve are identified, the difference in magnitude of effect at different exposure levels can be reflected in risk characterization.

It is important to clearly describe and quantitatively estimate the assumptions and uncertainties involved in the evaluation, where possible. Examples include natural variability in ecological characteristics and responses and uncertainties in the test system and extrapolations. The description and analysis of uncertainty in characterization of ecological effects are combined with uncertainty analyses for the other ecological risk assessment elements during risk characterization.

Additional Issues Related to the Analysis Phase

- Quantifying cumulative impacts and stress-response relationships for multiple stressors.
- Improving the prediction of ecosystem recovery.
- Improving the quantification of indirect effects.
- Describing stressor-response relationships for physical perturbations.
- Distinguishing ecosystem changes due to natural processes from those caused by man.

4. RISK CHARACTERIZATION

Risk characterization (figure 4) is the final phase of risk assessment. During this phase, the likelihood of adverse effects occurring as a result of exposure to a stressor are evaluated. Risk characterization contains two major steps: risk estimation and risk description. The stressor-response profile and the exposure profile from the analysis phase serve as input to risk estimation. The uncertainties identified during all phases of the risk assessment also are analyzed and summarized. The estimated risks are discussed by considering the types and magnitude of effects anticipated, the spatial and temporal extent of the effects, and recovery potential. Supporting information in the form of a weight-of-evidence discussion also is presented during this step. The results of the risk assessment, including the relevance of the identified risks to the original goals of the risk assessment, then are discussed with the risk manager.

4.1. Risk Estimation

Risk estimation consists of comparing the exposure and stressor-response profiles as well as estimating and summarizing the associated uncertainties.

4.1.1. Integration of Stressor-Response and Exposure Profiles

Three general approaches are discussed to illustrate the integration of the stressor-response and exposure profiles: (1) comparing single effect and exposure values; (2) comparing distributions of effects and exposure; and (3) conducting simulation modeling. Because these are areas of active research, particularly in the assessment of community- and landscape-level perturbations, additional integration approaches are likely to be available in the future. The final choice as to which approach will be selected depends on the original purpose of the assessment as well as time and data constraints.

Comparing Single Effect and Exposure Values

Many risk assessments compare single effect values with predicted or measured levels of the stressor. The effect values from the stressor-response profile may be used as is, or more commonly, uncertainty or safety factors may be used to adjust the value. The ratio or quotient of the exposure value to the effect value provides the risk estimate. If the quotient is one or more, an adverse effect is considered likely to occur. This approach, known as the Quotient Method (Barnthouse et al., 1986), has been used extensively to evaluate the risks of chemical stressors (Nabholz 1991; Urban and Cook, 1986). Although the Quotient Method is commonly used and accepted, it is the least probabilistic of the approaches described here. Also, correct usage of the Quotient Method is highly dependent on professional judgment, particularly in instances when the quotient approaches one. Greater insight into the magnitude of the effects expected at various levels of exposure can be obtained by evaluating the full stressor-response curve instead of a single point and by considering the frequency, timing, and duration of the exposure.

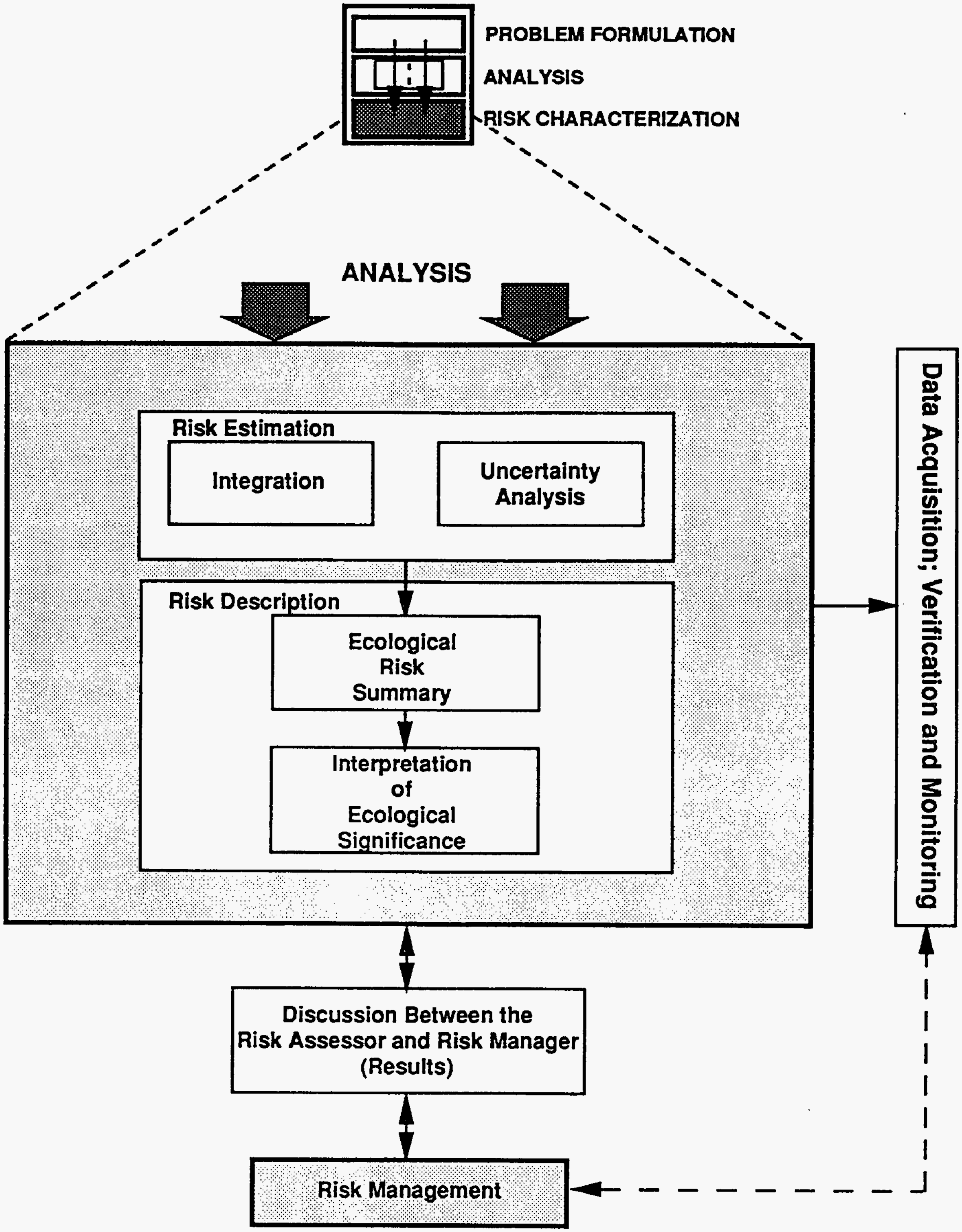

Figure 4. Risk Characterization

Comparing Distributions of Effects and Exposure

This approach uses distributions of effects and exposure (as opposed to single values) and thus makes probabilistic risk estimates easier to develop. Risk is quantified by the degree of overlap between the two distributions; the more overlap, the greater the risk. An example of this approach, Analysis of Extrapolation Error, is given in Barnthouse et al. (1986). To construct valid distributions, it is important that sufficient data amenable to statistical treatment are available.

Conducting Simulation Modeling

Simulation models that can integrate both the stressor-response profile and exposure profile are useful for obtaining probabilistic estimates of risk. Two categories of simulation models are used for ecological risk assessment: single-species population models are used to predict direct effects on a single population of concern using measurement endpoints at the individual level, while multi-species models include aquatic food web models and terrestrial plant succession models and are useful for evaluating both direct and indirect effects.

When selecting a model, it is important to determine the appropriateness of the model for a particular application. For example, if indirect effects are of concern, a model of community-level interactions will be needed. Direct effects to a particular population of concern may be better addressed with population models. The validation status and use history of a model also are important considerations in model selection. Although simulation models are not commonly used for ecological risk assessment at the present time, this is an area of active research, and the use of simulation models is likely to increase.

In addition to providing estimates of risks, simulation models also can be useful in discussing the results of the risk characterization to the risk manager. This dialogue is particularly effective when the relationship between risks to certain measurement endpoints and the assessment endpoint are not readily apparent (e.g., certain indirect effects and large-scale ecosystem-level disturbances).

4.1.2. Uncertainty

The uncertainty analysis identifies, and, to the extent possible, quantifies the uncertainty in problem formulation, analysis, and risk characterization. The uncertainties from each of these phases of the process are carried through as part of the total uncertainty in the risk assessment. The output from the uncertainty analysis is an evaluation of the impact of the uncertainties on the overall assessment and, when feasible, a description of the ways in which uncertainty could be reduced.

A complete discussion of uncertainty is beyond the scope of this report, and the reader is referred to the works of Finkel (1990), Holling (1978), and Suter (1990b). However, a brief discussion of the major sources of uncertainty in ecological risk assessment is appropriate. For illustrative purposes, four major areas of uncertainty are presented below. These are not discrete categories, and overlap does exist among them. Any specific risk assessment may have uncertainties in one or all of these categories.

Conceptual Model Formulation

As noted earlier, the conceptual model is the product of the problem formulation phase, which, in turn, provides the foundation for the analysis phase and the development of the exposure and stressor-response profiles. If incorrect assumptions are made during conceptual model development regarding the potential effects of a stressor, the environments impacted, or the species residing within those systems, then the final risk assessment will be flawed. These types of uncertainties are perhaps the most difficult to identify, quantify, and reduce.

Information and Data

Another important contributor of uncertainty is the incompleteness of the data or information upon which the risk assessment is based. In some instances, the risk assessment may be halted temporarily until additional information is obtained. In other cases, certain basic information such as life history data may be unobtainable with the resources available to the risk assessment. In yet other cases, fundamental understanding of some natural processes with an ecosystem may be lacking. In instances where additional information cannot be obtained, the role of professional judgment and judicial use of assumptions are critical for the completion of the assessment.

Stochasticity (Natural Variability)

Natural variability is a basic characteristic of stressors and ecological components as well as the factors that influence their distribution (e.g., weather patterns, nutrient availability). As noted by Suter (1990b), of all the contributions to uncertainty, stochasticity is the only one that can be acknowledged and described but not reduced. Natural variability is amenable to quantitative analyses, including Monte Carlo simulation and statistical uncertainty analysis (O'Neill and Gardner, 1979; O'Neill et al., 1982).

Error

Errors can be introduced through experimental design or the procedures used for measurement and sampling. Such errors can be reduced by adherence to good laboratory practices and adherence to established experimental protocols. Errors also can be introduced during simulation model development. Uncertainty in the development and use of models can be reduced through sensitivity analyses, comparison with similar models, and field validation.

In summary, uncertainty analyses provide the risk manager with an insight into the strengths and weaknesses of an assessment. The uncertainty analysis also can serve as a basis for making rational decisions regarding alternative actions as well as for obtaining additional information to reduce uncertainty in the risk estimates.

4.2. Risk Description

Risk description has two primary elements. The first is the ecological risk summary, which summarizes the results of the risk estimation and uncertainty analysis and assesses confidence in the risk estimates through a discussion of the weight of evidence. The second element is interpretation of ecological significance, which describes the magnitude of the identified risks to the assessment endpoint.

4.2.1. Ecological Risk Summary

The ecological risk summary summarizes the results of the risk estimation and discusses the uncertainties associated with problem formulation, analysis, and risk characterization. Next, the confidence in the risk estimates is expressed through a weight-of-evidence discussion. The ecological risk summary may conclude with an identification of additional analyses or data that might reduce the uncertainty in the risk estimates. These three aspects of the ecological risk summary are discussed in the following sections.

Summary of Risk Estimation and Uncertainty

Ideally, the conclusions of the risk estimation are described as some type of quantitative statement (e.g., there is a 20 percent chance of 50 percent mortality). However, in most instances, likelihood is expressed in a qualitative statement (e.g., there is a high likelihood of mortality occurring). The uncertainties identified during the risk assessment are summarized either quantitatively or qualitatively, and the relative contribution of the various uncertainties to the risk estimates are discussed whenever possible.

Weight of Evidence

The weight-of-evidence discussion provides the risk manager with insight about the confidence of the conclusions reached in the risk assessment by comparing the positive and negative aspects of the data, including uncertainties identified throughout the process. The considerations listed below are useful in a weight-of-evidence discussion:

- The sufficiency and quality of the data. A risk assessment conducted with studies that completely characterize both the effects and exposure of the stressor has more credibility and support than an assessment that contains data gaps. It is important to state if the data at hand were sufficient to support the findings of the assessment. In addition, data validity (e.g., adherence to protocols, having sufficient replications) is an important facet of the weight-of-evidence analysis.

- Corroborative information. Here the assessor incorporates supplementary information that is relevant to the conclusions reached in the assessment. Examples include reported incidences of effects elicited by the stressor (or similar stressor) and studies demonstrating agreement between model predictions and observed effects.

- Evidence of causality. The degree of correlation between the presence of a stressor and some adverse effect is an important consideration for many ecological risk assessments. This correlation is particularly true when an assessor is attempting to establish a link between certain observed field effects and the cause of those effects. Further discussions of the evaluation of causal relationships may be found in the section on characterization of ecological effects (section 3.2.2.).

Identification of Additional Analyses

The need for certain analyses may not be identified until after the risk estimation step. For example, the need to analyze the risks to a fish population (an assessment endpoint) due to an indirect effect such as zooplankton mortality (a measurement endpoint) may not be established until after the risk to zooplankton has been characterized. In such cases, another iteration through analysis or even problem formulation may be necessary.

4.2.2. Interpretation of Ecological Significance

The interpretation of ecological significance places risk estimates in the context of the types and extent of anticipated effects. It provides a critical link between the estimation of risks and the communication of assessment results. The interpretation step relies on professional judgment and may emphasize different aspects depending on the assessment. Several aspects of ecological significance that may be considered include the nature and magnitude of the effects, the spatial and temporal patterns of the effects, and the potential for recovery once a stressor is removed.

Nature and Magnitude of the Effects

The relative significance of different effects may require further interpretation, especially when changes in several assessment or measurement endpoints are observed or predicted. For example, if a risk assessment is concerned with the effects of stressors on several ecosystems in an area (such as a forest, stream, and wetland), it is important to discuss the types of effects associated with each ecosystem and where the greatest impact is likely to occur.

The magnitude of an effect will depend on its ecological context. For example, a reduction in the reproductive rate may have little effect on a population that reproduces rapidly, but it may dramatically reduce the numbers of a population that reproduces slowly. Population-dependent and -independent factors in the ecosystem also may influence the expression of the effect.

Finally, it is important to consider the effects in the context of both magnitude and the likelihood of the effect occurring. In some cases, the likelihood of exposure to a stressor may be low, but the effect resulting from the exposure would be devastating. For example, large oil spills may not be common, but they can cause severe and extensive effects in ecologically sensitive areas.

Spatial and Temporal Patterns of the Effects

The spatial and temporal distributions of the effect provide another perspective important to interpreting ecological significance. The extent of the area where the stressor is likely to occur is a primary consideration when evaluating the spatial pattern of effects. Clearly, a stressor distributed over a larger area has a greater potential to affect more organisms than one confined to a small area. However, a stressor that adversely affects small areas can have devastating effects if those areas provide critical resources for certain species. In addition, adverse effects to a resource that is small in scale (e.g., acidic bogs) may have a small spatial effect but may represent a significant degradation of the resource because of its overall scarcity.

The duration of any effect is dependent on the persistence of the stressor as well as how often the stressor is likely to occur in the environment. It is important to remember that even short-term effects can be devastating if such exposure occurs during critical life stages of organisms.

Recovery Potential

A discussion of the recovery potential may be an integral part of risk description, although the need for such an evaluation will depend on the objective of the assessment and the assessment endpoints. An evaluation of the recovery potential may require additional analyses, as discussed in section 3.1., and will depend on the nature, duration, and extent of the stressor.

Depending on the assessment objectives, all of the above factors may be used to place the risks into the broader ecological context. This discussion may consider the ramifications of the effects on other ecological components that were not specifically addressed in the assessment. For example, an assessment that focused on the decline of alligator populations may include a discussion of the broader ecological role of the alligator, such as the construction of wallows that act as water reservoirs during droughts. In this way, the potential effects on the community that depends on the alligator wallows can be brought out in risk characterization.

4.3. Discussion Between the Risk Assessor and Risk Manager (Results)

Risk characterization concludes the risk assessment process and provides the basis for discussions between the risk assessor and risk manager that pave the way for regulatory decision-making. The purpose of these discussions is to ensure that the results of the risk assessment are clearly and fully presented and to provide an opportunity for the risk manager to ask for any necessary clarification. Proper presentation of the risk assessment is essential to reduce the chance of over- or under-interpretation of the results. To permit the risk manager to evaluate the full range of possibilities contained in the risk assessment, it is important that the risk assessor provide the following types of information:

- the goal of the risk assessment;
- the connection between the measurement and assessment endpoints;
- the magnitude and extent of the effect, including spatial and temporal considerations and, if possible, recovery potential;
- the assumptions used and the uncertainties encountered during the risk assessment;
- a summary profile of the degrees of risk as well as a weight-of-evidence analysis; and
- the incremental risk from stressors other than those already under consideration (if possible).

The results of the risk assessment serve as input to the risk management process, where they are used along with other inputs defined in EPA statutes, such as social and economic concerns, to evaluate risk management options.

In addition, based on the discussions between the risk assessor and risk manager, follow-on activities to the risk assessment may be identified, including monitoring, studies to verify the predictions of the risk assessment, or the collection of additional data to reduce the uncertainties in the risk assessment. While a detailed discussion of the risk management process is beyond the scope of this report, consideration of the basic principles of ecological risk assessment described here will contribute to a final product that is both credible and germane to the needs of the risk manager.

Additional Issues Related to the Risk Characterization Phase

- Predicting the time required for an ecological component to recover from a stressor.
- Combining chemical and nonchemical stressors in risk characterization.
- Incorporating critical effect levels into risk characterization.
- Better quantification of uncertainty.
- Developing alternative techniques for expressing uncertainty in risk characterization.

5. KEY TERMS

assessment endpoint--An explicit expression of the environmental value that is to be protected.

characterization of ecological effects--A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor to cause adverse effects under a particular set of circumstances.

characterization of exposure--A portion of the analysis phase of ecological risk assessment that evaluates the interaction of the stressor with one or more ecological components. Exposure can be expressed as co-occurrence, or contact depending on the stressor and ecological component involved.

community--An assemblage of populations of different species within a specified location in space and time.

conceptual model--The conceptual model describes a series of working hypotheses of how the stressor might affect ecological components. The conceptual model also describes the ecosystem potentially at risk, the relationship between measurement and assessment endpoints, and exposure scenarios.

direct effect--An effect where the stressor acts on the ecological component of interest itself, not through effects on other components of the ecosystem (compare with definition for indirect effect).

ecological component--Any part of an ecological system, including individuals, populations, communities, and the ecosystem itself.

ecological risk assessment--The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.

ecosystem--The biotic community and abiotic environment within a specified location in space and time.

exposure--Co-occurrence of or contact between a stressor and an ecological component.

exposure profile--The product of characterization of exposure in the analysis phase of ecological risk assessment. The exposure profile summarizes the magnitude and spatial and temporal patterns of exposure for the scenarios described in the conceptual model.

exposure scenario--A set of assumptions concerning how a exposure may take place, including assumptions about the exposure setting, stressor characteristics, and activities that may lead to exposure.

indirect effect--An effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest.

measurement endpoint--A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint. Measurement endpoints are often expressed as the statistical or arithmetic summaries of the observations that comprise the measurement.

median lethal concentration (LC_{50})--A statistically or graphically estimated concentration that is expected to be lethal to 50 percent of a group of organisms under specified conditions (ASTM, 1990).

no observed effect level (NOEL)--The highest level of a stressor evaluated in a test that does not cause statistically significant differences from the controls.

population--An aggregate of individuals of a species within a specified location in space and time.

recovery--The partial or full return of a population or community to a condition that existed before the introduction of the stressor.

risk characterization--A phase of ecological risk assessment that integrates the results of the exposure and ecological effects analyses to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. The ecological significance of the adverse effects is discussed, including consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery.

stressor--Any physical, chemical, or biological entity that can induce an adverse response.

stressor-response profile--The product of characterization of ecological effects in the analysis phase of ecological risk assessment. The stressor-response profile summarizes the data on the effects of a stressor and the relationship of the data to the assessment endpoint.

trophic levels--A functional classification of taxa within a community that is based on feeding relationships (e.g., aquatic and terrestrial green plants comprise the first trophic level and herbivores comprise the second).

xenobiotic--A chemical or other stressor that does not occur naturally in the environment. Xenobiotics occur as a result of anthropogenic activities such as the application of pesticides and the discharge of industrial chemicals to air, land, or water.

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